UNITED STATES DEPARTMENT OF COMMERCE
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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 09/039,789 | 03/16/98 | CARVER | |

IM41/0303

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EXAMINER: SODERQUIST, A

| ART UNIT | PAPER NUMBER |
|---|---|
| 1743 | |

DATE MAILED: 03/03/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/039789 | Carver, Jr. et al. |
| **Examiner** | **Group Art Unit** |
| Sodergquist | 1743 |

*—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—*

**Period for Response**

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

**Status**

☒ Responsive to communication(s) filed on 3-16-98.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

**Disposition of Claims**

☒ Claim(s) 27-35 is/are pending in the application.

Of the above claim(s)_____ is/are withdrawn from consideration.

☐ Claim(s)_____ is/are allowed.

☒ Claim(s) 27-35 is/are rejected.

☐ Claim(s)_____ is/are objected to.

☐ Claim(s)_____ are subject to restriction or election requirement.

**Application Papers**

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on_____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on_____ is/are objected to by the Examiner.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119 (a)-(d)**

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)_____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:_____.

**Attachment(s)**

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☒ Notice of References Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other_____

**Office Action Summary** Arlen Sodergquist

1. The disclosure is objected to because of the following informalities: the status of the parent 08/370,023 application should be updated.

Appropriate correction is required.

2. Claims 27 - 35 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the plurality of lysing agents need to be positively recited as a limitation of the apparatus to provide antecedent basis for the selecting step in claim 27 and the control means of claim 35.

3. It is noted that the inventorship was changed in the parent application. Since the application was filed with a copy of the original declaration and there was no request to delete inventors, examiner is assuming that the instant inventorship includes two inventors.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 27 - 35 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Yamamoto in view of Kabata and Taylor. In the figures and associated discussion Yamamoto teaches an automated blood analyzer and method for making blood particle analyses. Yamamoto teaches at least one pump (102,111,162) in fluid communication with a mixing chamber (113-115) and a source diluent. A sample (101) is removed from a sample container by a sample probe

(117,161) and the at least one pump transfers the sample and diluent to the mixing chambers. Since the fluid flow arrows of figures 2 and 5 show pumps 102, 111, and 162 as capable of both suction and positive pressure, they are positive displacement pumps. Two different lysing reagents (141,142) are also transferred to the mixing chambers by a vacuum pump. The blood sample is analyzed for particles through a sensing orifice (158). The device has a controller (figure 3) for controlling the device and analyzing the result. Also Figure 4 shows that the result is obtainable in around 47 seconds. Yamamoto does not teach a multiple species database having different lysing compositions for each species which are mixed for blood samples from the different species.

In the paper Kabata teaches the analysis of the hematologic values of peripheral blood from normal adult rabbits using five different automated flow cytometers. During the analysis the software designed for human blood analysis was used. In the second paragraph of page 613 Kabata teaches that it is known that rabbit blood cells are known to differ from human blood cells in several aspects and suggests adapting the software for animal blood. Pages 614 - 615 discuss how the different automated systems work to obtain the various blood cell populations. It is noted that most of the automated systems incorporate a lysing reagent in the various methods. The rest of the article reports the results and discusses its significance. Of importance to the instant claims is the discussion on page 618 regarding the problems in determining the white blood cell differential counts. The first paragraph also teaches that the leukocytes of rabbits have several morphologic features that differ from human leukocytes. In the second to last paragraph Kabata teaches that automatic counting of **all** white blood cell sub-populations in animals would require different software. Also taught was the failure of Technicon software designed for use with rat or dog blood to give as reliable of results for rabbit blood as the software designed for humans. Since the Technicon software for rats and dogs give different results, the two sets of software are different.

In the paper Taylor compares several treatment procedures for preparing different cell populations for flow cytometric analysis. They teach that although each works, one of the methods works better than the others in flow cytometric analysis.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate software/database for multiple species including differences in lytic agents as taught by Kabata into the Yamamoto device and method and control the device to perform the optimum process for each different species because one of ordinary skill in the art would have recognized that the utility of the device would be increased by the ability to process blood from multiple species and that due to differences in the morphology of the blood cells of the different species an optimized process including reagent sample compositions would have been required for each species.

6. Claims 27 - 35 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cellect Hematology in view of Kabata and Taylor. In the figures and associated discussion Cellect Hematology teaches a fully automated blood analyzer and method for making blood particle analyses. In the figure on pages 5 - 6 Cellect Hematology shows the major systems of the instrument including at least one positive displacement syringe pump and stepper motor in fluid communication with a mixing chamber (dilution manifold) and a source diluent. A sample is removed from a sample container by a sample probe and the at least one pump transfers the sample and diluent to the dilution manifold. A lysing reagent is also provided during an analysis. The blood sample is analyzed for particles through a sensing orifice (counting manifold). The device has a controller (microprocessor) for controlling the device and analyzing the result. On page 1 in the first column, Cellect Hematology teaches the ease in adapting the instrument to add on new tests. Cellect Hematology does not teach a multiple species database having different lysing compositions for each species which are mixed for blood samples from the different species.

In the paper Kabata teaches the analysis of the hematologic values of peripheral blood from normal adult rabbits using five different automated flow cytometers. During the analysis the software designed for human blood analysis was used. In the second paragraph of page 613 Kabata teaches that it is known that rabbit blood cells are known to differ from human blood cells in several aspects and suggests adapting the software for animal blood. Pages 614 - 615 discuss how the different automated systems work to obtain the various blood cell populations. It is

noted that most of the automated systems incorporate a lysing reagent in the various methods. The rest of the article reports the results and discusses its significance. Of importance to the instant claims is the discussion on page 618 regarding the problems in determining the white blood cell differential counts. The first paragraph also teaches that the leukocytes of rabbits have several morphologic features that differ from human leukocytes. In the second to last paragraph Kabata teaches that automatic counting of **all** white blood cell sub-populations in animals would require different software. Also taught was the failure of Technicon software designed for use with rat or dog blood to give as reliable of results for rabbit blood as the software designed for humans. Since the Technicon software for rats and dogs give different results, the two sets of software are different.

In the paper Taylor compares several treatment procedures for preparing different cell populations for flow cytometric analysis. They teach that although each works, one of the methods works better than the others in flow cytometric analysis.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate software/database for multiple species including differences in lytic agents as taught by Kabata into the Cellect Hematology method and device and control the device to perform the optimum process for each different species because one of ordinary skill in the art would have recognized that the utility of the device would be increased by the ability to process blood from multiple species and that due to differences in the morphology of the blood cells of the different species an optimized process including reagent sample compositions would have been required for each species.

7. Claims 27 - 35 are rejected under 35 U.S.C. § 103 as being unpatentable over Yamamoto in view of Carver (US 5,316,725). In the figures and associated discussion Yamamoto teaches an automated blood analyzer and method for making blood particle analyses. Yamamoto teaches at least one pump (102,111,162) in fluid communication with a mixing chamber (113-115) and a source diluent. A sample (101) is removed from a sample container by a sample probe (117,161) and the at least one pump transfers the sample and diluent to the mixing chambers. Since the fluid flow arrows of figures 2 and 5 show pumps 102, 111, and 162 as capable of both suction and

positive pressure, they are positive displacement pumps. Two different lysing reagents (141,142) are also transferred to the mixing chambers by a vacuum pump. The blood sample is analyzed for particles through a sensing orifice (158). The device has a controller (figure 3) for controlling the device and analyzing the result. Also Figure 4 shows that the result is obtainable in around 47 seconds. Yamamoto does not teach a multiple species database having different lysing compositions for each species which are mixed for blood samples from the different species.

In the patent Carver teaches different compositions of lysing agents for performing white blood cell analysis. Column 13 discusses multispecies applications of the lysing agents teaching that due to variations in the physiology of the white blood cell membrane the lysing reagent composition must be optimized for each species. Table 1 shows the differences in the ratios of the two lytic agents in the composition, the amount of blood sample to the lytic composition, and the amount of diluent to the lytic composition for two species. Example 4 shows how the ratios can be optimized by creating various mixtures from the individual lytic agents and diluent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a database for multiple species and multiple lytic agents as taught by Carver into the Yamamoto method and device and control the device to form the various compositions for the different species because one of ordinary skill in the art would have recognized that the utility of the device would be increased by the ability to process blood from multiple species by forming optimized reagent sample compositions for each species.

8. Claims 27 - 35 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cellect Hematology in view of Carver. In the figures and associated discussion Cellect Hematology teaches a fully automated blood analyzer and method for making blood particle analyses. In the figure on pages 5 - 6 Cellect Hematology shows the major systems of the instrument including at least one positive displacement syringe pump and stepper motor in fluid communication with a mixing chamber (dilution manifold) and a source diluent. A sample is removed from a sample container by a sample probe and the at least one pump transfers the sample and diluent to the dilution manifold. A lysing reagent is also provided during an analysis. The blood sample is analyzed for particles through a sensing orifice (counting manifold). The device has a controller

(microprocessor) for controlling the device and analyzing the result. On page 1 in the first column, Cellect Hematology teaches the ease in adapting the instrument to add on new tests. Cellect Hematology does not teach a multiple species database having different lysing compositions for each species which are mixed for blood samples from the different species.

In the patent Carver teaches different compositions of lysing agents for performing white blood cell analysis. Column 13 discusses multispecies applications of the lysing agents teaching that due to variations in the physiology of the white blood cell membrane the lysing reagent composition must be optimized for each species. Table 1 shows the differences in the ratios of the two lytic agents in the composition, the amount of blood sample to the lytic composition, and the amount of diluent to the lytic composition for two species. Example 4 shows how the ratios can be optimized by creating various mixtures from the individual lytic agents and diluent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a database for multiple species and multiple lytic agents as taught by Carver into the Cellect Hematology analyzer and method and control the device to form the various compositions for the different species because one of ordinary skill in the art would have recognized that the utility of the device would be increased by the ability to process blood from multiple species by forming optimized reagent sample compositions for each species.

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claim 35 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11 - 14 of U.S. Patent No. 5,728,351. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims totally encompass the patented claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (703) 308-3989. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 305-7718 for Official papers prior to mailing of a final Office action, (703) 305-3599 for Official papers after mailing of a final Office action, or (703) 305-7719 for unofficial or draft papers. The above fax numbers will allow the papers to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Arlen Soderquist

February 26, 1999

ARLEN SODERQUIST
PRIMARY EXAMINER